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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/451,641	11/30/1999	Danchen Gao	PC10664	9327

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EXAMINER	
TRAN, SUSAN T	
ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/451,641	GAO ET AL.	
	Examiner	Art Unit	
	S. Tran	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 December 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10,12-75,84 and 86-90* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10,12-75,84 and 86-90* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/22/08;01/26/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 16 and 29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 16 contains the trademark/trade name "Celutab™" and "Rexcel™". Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe the diluents and, accordingly, the identification/description is indefinite.

Claim 29 contains the trademark/trade name "Stearowet™". Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to

identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe the lubricants and, accordingly, the identification/description is indefinite.

There is no description in the specification of the exact ingredients of "Stearowet™", "Celutab™", and "Rexcel™" which can change over time.

Claim Rejections - 35 USC § 103

Claims 1-10, 12-75, 84 and 86-90 are rejected under 35 U.S.C. 103(a) as being unpatentable over Franson et al. US 5,591,456, in view of Black EP 0 863 134 and AAPS Annual Meeting Contributed Papers Abstracts (AAPS).

Franson teaches a dispersible particle comprising crystalline NSAID having hydroxypropyl cellulose adsorbed on the surface thereof in an amount sufficient to maintain an effective average particle size of less than about 1000 nm, and at least 99% of the particle has size less than 400 nm (abstract; and column 3, lines 56 through column 4, lines 1-4).

Franson does not teach the claimed NSAID compound, such as celecoxib.

Black teaches a compound useful as a Cox-2 inhibitor for pain relief, fever and inflammation of a variety symptoms disclosed on page 3, lines 29-36. The compound can be administered orally in the form of tablets, troches, lozenges, or capsules (page 4, lines 1-12). The tablets comprise active ingredient in admixture with excipients, *e.g.*,

diluents, disintegrants, binding agents, wetting agents, and surfactant (page 4, lines 15-38). The active agent is present in an amount of 10 to 250 mg. The carrier material may vary from about 5 to about 95% (page 5, lines 39-58). The dosage can be administered once or twice a day, and will provide effective $T_{1/2}$ over a 24 hours period (page 5, lines 22-27). Example 2 discloses the amount of excipients use in a tablet.

Thus, it would have been obvious for one of ordinary skill in the art to modify the NSAID formulation of Franson using the COX-2 compound of Black, because Black teaches a COX-2 compound that is proved useful as an alternative to conventional NSAIDs (page 3, lines 41-46), because Black teaches COX-2 as a partial or complete substitute for conventional NSAIDs, and because Franson teaches a particle dispersion suitable for a wide variety of active agents including a number of NSAIDs.

Franson further does not teach the claimed properties, such as bioavailability, C_{max}, and T_{max}.

AAPS teaches a celecoxib (Cox-2 inhibitor) formulation that exhibits an unchanged C_{max} value of 1527 and 1077 ng/mL, and a T_{max} of 1.9 hours (see page D32). At page 3469, the AAPS reference teaches a COX-2 composition that is rapidly absorbed with a T_{max} of 1.9 hours, and eliminated with a $t_{1/2}$ of about 15 hours. Accordingly, it would have been obvious to one of ordinary skill in the art to optimize the parameter of Franson in view of Black and AAPS to obtain the claimed properties. This is because AAPS teaches properties of a COX-2 formulation that is useful in pharmaceutical art.

Response to Arguments

Applicant's arguments filed 01/26/09 have been fully considered but they are not persuasive.

Applicant argues that the use of the trade names Celutab ™, Rexcel ™ and Stearowet ™ is permissible under MPEP 608.01(v) because these trade names were well-known and satisfactorily defined in the literature at the time the present application was filed.

However, in response to the applicant's arguments, first, it is noted that nowhere does the specification, or any cited literature, provide the exact ingredients for the trade name "Stearowet™", "Celutab™", or "Rexcel™". In patent specifications, every element or ingredient of the product should be set forth in positive, exact, intelligible language, so that there will be no uncertainty as to what is meant. *Ex Parte Kattwinkle*, 12 USPQ 11 (Bd. App. 1931). Further, the relationship between a trademark and the product it identifies is indefinite, uncertain, and arbitrary, because the formula or characteristics of the product may change from time to time, and yet, it may continue to be sold under the same trademark. Accordingly, the use of the trademark/trade name "Stearowet™", "Celutab™", and "Rexcel™" in the claims is improper. Therefore, the rejection is maintained.

Applicant argues that the composite particle taught in Franson is not the particulate celecoxib of the present claims because Franson teaches a composite particle consisting essentially of naproxen and hydroxypropyl cellulose.

Applicant argues that like Franson, Black does not teach the claimed compound celecoxib. Rather Black teaches a different COX-2 inhibitor and various compositions thereof.

Applicant argues that AAPS reference provides no teaching as to the nature of the suspension (is it an aqueous suspension? are there excipients and/or suspending agents present?). Second, besides disclosing that the capsules contained 300 mg of celecoxib, the AAPS reference fails to disclose any further information regarding this dosage form. Specifically, the AAPS reference fails to teach whether the celecoxib in the capsule was in the form of solid particles, in a suspension, or in solution; and whether the celecoxib in the capsule was formulated in any way, including whether there were excipients present and, if so, identifying those excipients. Finally, the AAPS reference is silent as to the particle size distribution of the celecoxib in either the suspension or the capsule. Accordingly, it is respectfully submitted that the AAPS reference fails to teach a formulation at all.

However, in response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Further, in response to applicant's argument that *Franson does not teach particulate celecoxib*, it is noted that Franson is cited in view of Black for the teaching of a COX-2 compound that is proved useful as an alternative to conventional NSAIDs (page 3, lines 41-46). Moreover, AAPS teaches celecoxib is a

well known COX-2 inhibitor. AAPS is also relied upon for the teaching of properties of celecoxib that is found useful in pharmaceutical art. Accordingly, one of ordinary skill in the art would have been motivated to, by routine experimentation optimize the compositions of Franson and Black to obtain a celecoxib formulation with properties useful for the same purpose as the claimed invention, namely, a useful COX-2 inhibitor formulation suitable for the treatment of condition or disorder in a subject where treatment with a cyclooxygenase-2 inhibitor is indicated.

Applicant argues that the office has engaged in impermissible hindsight, piercing together teachings of the prior art using the Applicant's specification as a blueprint.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to S. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-F 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. Tran/
Primary Examiner, Art Unit 1615